This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92(c).

1. Submitter's name, address, telephone number, contact person, and date summary prepared;

a. Applicant: Advance Medial Optics, Inc. (AMO®)
1700 E. St. Andrew Place
Santa Ana, CA 92799

b. Contact Person: Pam Schaub
Director, Worldwide Regulatory Affairs, AMO®
1700 E. St. Andrew Place
Santa Ana, CA 92799
714-247-8603 (phone)
714-247-8677 (fax)

c. Date Summary Prepared: March 11, 2005

2. Name of device, including trade name and classification name:

a. Trade/Proprietary Name: SOVEREIGN® High Vacuum Pack
SOVEREIGN® Compact High Vacuum Pack

b. Classification Name: Phacofragmentation System

c. Device Classification: Class II per 21 CFR 886.4670

d. Product Code: HQC

3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

Company:	Advanced Medical Optics (AMO®)
Device:	SOVEREIGN® Phaco Pack
510(k):	K981116
Date Cleared:	May 19, 1998

Company:	Staar Surgical Company
Device:	Staar Surge-free Aspiration Adapter
510(k):	K020734
Date Cleared:	May 16, 2002

4. **A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):**

The SOVEREIGN® High Vacuum Pack and the SOVEREIGN® Compact High Vacuum Pack are accessory kits indicated for use with the SOVEREIGN® phacoemulsification machine and the SOVEREIGN® Compact phacoemulsification machine, respectively, to perform an irrigation/aspiration (I/A) procedure or a phacoemulsification procedure during cataract surgery. The tubing assembly component of the kit incorporates a flow restriction feature for preventing/neutralizing post occlusion surge following an occlusion break at the distal end of a phaco tip. The materials, basic scientific concepts, physical properties and intended use of the device kits are similar to those of the identified predicate devices.

5. **Statement of intended use:**

The SOVEREIGN® High Vacuum Pack is indicated for use with the SOVEREIGN® phacoemulsification machine. The SOVEREIGN® High Vacuum pack includes a filter protected flow restriction orifice used during cataract surgery to minimize vacuum surges in the aspiration line.

The SOVEREIGN® Compact High Vacuum Pack is indicated for use with the SOVEREIGN® Compact phacoemulsification machine. The SOVEREIGN® Compact High Vacuum pack includes a filter protected flow restriction orifice used during cataract surgery to minimize vacuum surges in the aspiration line.

6. **Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.**

The technological characteristics of the SOVEREIGN® High Vacuum Pack were compared to those of the predicate devices and were found to be equivalent with respect to the materials, method of sterilization, intended use, and mode of operation.

7. **Brief summary of nonclinical tests and results:**

Bench testing was conducted which verified that the performance characteristics (flow resistance and chamber maintenance) associated with the SOVEREIGN® High Vacuum Pack were equivalent to that of the predicate devices.

8. **Conclusions**

AMO® has demonstrated through its evaluation of the SOVEREIGN® High Vacuum Pack that the device is equivalent to the predicate devices with respect to intended use, technological characteristics, and safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 5 2005

Advanced Medical Optics, Inc.
% Pam Schaub
1700 East St. Andrew Pl.
Santa Ana, CA 92705

Re: K050648
Trade/Device Name: Sovereign High Vacuum Pack,
Sovereign Compact High Vacuum Pack
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation system
Regulatory Class: Class II
Product Code: HQC
Dated: March 11, 2005
Received: March 15, 2005

Dear Ms. Schaub:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 2

INDICATIONS FOR USE

510(k) Number: K050648 (To Be Assigned By FDA)

Device Trade Name: SOVEREIGN® High Vacuum Pack
SOVEREIGN® Compact High Vacuum Pack

Indications For Use: The SOVEREIGN® High Vacuum Pack is indicated for use with the SOVEREIGN® phacoemulsification machine. The SOVEREIGN® High Vacuum pack includes a filter protected flow restriction orifice used during cataract surgery to minimize vacuum surges in the aspiration line.

The SOVEREIGN® Compact High Vacuum Pack is indicated for use with the SOVEREIGN® Compact phacoemulsification machine. The SOVEREIGN® Compact High Vacuum pack includes a filter protected flow restriction orifice used during cataract surgery to minimize vacuum surges in the aspiration line.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Clay R Buttermore

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K050648

Page 1 of 1